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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,664	01/22/2004	David J. Beebe	282.033	5152

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,664	BEEBE ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/6/2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) *9,17,20 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-16 and 18* is/are rejected.

7)☒ Claim(s) *21-24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/6/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 9/25/2006.

2. In the reply, the Applicant amended claims 1, 5, 10, 14, 18 and 22 and cancelled claim 19. Claims 9, 17, 20, and 25 remain withdrawn.

3. Additionally the Applicant submitted formal drawings obviating the previous objection to the drawings and amended the specification obviating the previous objection to the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6, 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by van Lintel, hereafter "Lintel" (5224843). Lintel discloses a microfluidic device (Fig 1) for delivering a drug to an individual comprising: a reservoir (15); an output needle (10; col 3, lns 37-38) having an input in communication with the reservoir and an output receivable within the individual; and a pressure source (13) engageable with the reservoir and having an adjustable configuration responsive to a predetermined fluid

between a first configuration and a second configuration (col 3, lns 45-50; wherein the Examiner notes that the Applicant's claim limitations do not require the pressure source to *directly respond* to a predetermined fluid, rather, a device may have a sensor in communication with the pressure source that measures a status of a predetermined fluid, such as the sugar level in blood, and based upon the status tells the pressure source to move from a first configuration to a second configuration urging fluid from the output needle); further comprising a flexible membrane (12) isolating the pressure source from the reservoir; further comprising a valve (18) operatively connecting the input of the output needle and the reservoir (Fig 1-2; wherein the valve defines a chamber (18d) having an input (col 4, lns 38-40) communicating with the reservoir and an output (col 4, lns 38-43) communicating with the input of the output needle; wherein the valve includes a flexible membrane (18a) and a trigger (18c) disposed in the trigger receiving portion (Fig 1) in the chamber of the valve and having a first configuration (col 4, lns 26-50) preventing the flow of the drug through the chamber and a second configuration (col 4, lns 26-50) allowing the flow of the drug through the chamber; further comprising a first sensing needle (10; col 3, lns 37-38) having an input receivable in the individual and an output (3) within the trigger receiving portion of the chamber (Fig 1), the first sensing needle being capable of allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber; wherein the output needle is removable from the body (10; col 3, lns 37-38).

6. Claims 1, 2, 10-12, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckenhoff et al (4552561). Eckenhoff et al discloses a microfluidic device

(Fig 8) for delivering a drug to an individual comprising: a reservoir (25); an output needle (22) having an input in communication with the reservoir and an output receivable within the individual; and a pressure source (18) engageable with the reservoir and having an adjustable configuration responsive to a predetermined fluid between a first configuration and a second configuration; further comprising a flexible membrane (10) isolating the pressure source from the reservoir; wherein the output needle is removable from the body (Fig 2, 8); further including an adhesive (6) for fixing the body to the individual; and a pressure source including a hydrogel member (18) expandable in response to exposure to a predetermined physical property (col 4, lns 29-35; col 5, lns 12-col 6, lns 28) and engageable with the reservoir to urge the drug from the reservoir through the output needle as the hydrogel member expands (col 4, lns 29-35; col 5, lns 12-col 6, lns 28; Figs 8, 13).

7. Claims 1-3, 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Couvillon, Jr. et al (2004/0068224). Couvillon, Jr. et al discloses a microfluidic device (Fig 3) for delivering a drug to an individual comprising: a reservoir (124); an output needle (120; [0051]) having an input in communication with the reservoir and an output receivable within the individual; and a pressure source (112, 114) engageable with the reservoir and having an adjustable configuration responsive to a predetermined fluid between a first configuration and a second configuration (Fig 3, 7, [0080]; wherein the Examiner notes that the Applicant's claim limitations allow for a device with a sensor sensing a predetermined fluid or a characteristic of a predetermined fluid and then relaying the results to controller and then to a pressure source to actuate the pressure

source from a first to second configuration); further comprising a flexible membrane (117) isolating the pressure source from the reservoir; a valve operable connecting the input of the output needle and the reservoir (158); wherein the output needle is removable from the body ([0051]); and a pressure source including a hydrogel member (112) expandable in response to exposure to a predetermined physical property ([0031-0038; 0044]; wherein the Examiner notes that an electrical current is a predetermined physical property) and engageable with the reserviour to urge the drug from the reservoir through the output needle as the hydrogel member expands (Fig 3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel. Lintel discloses the invention substantially as claimed except for expressly disclosing a second sensing needle having an input receivable in the individual and an output within the trigger receiving portion of the chamber, the second sensing needle allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a second sensing needle having an input receivable in the individual and an output within the trigger receiving portion of the chamber, the second sensing needle allowing physiological fluids to pass

from the individual to the trigger receiving portion of the chamber because the Applicant has not disclosed that having a second sensing needle provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the single sensing needle of Lintel because it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Therefore, it would have been an obvious matter of design choice to modify Lintel to obtain the invention as specified in claim 7.

10. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel in view of Beebe et al (6523559). Lintel discloses the invention substantially as claimed except for wherein the trigger includes a hydrogel post, the hydrogel post expandable in response to exposure to a predetermined condition. Beebe et al teaches that it is known to have wherein the trigger includes a hydrogel post (56), the hydrogel post expandable in response to exposure to a predetermined condition (col 5, lns 29-67) for the purpose of having a self-regulating microfluidic device responsive to changes in value of a solution to regulate the feedback to compensate and return the value of the solution to the desired level without the need for any external power sources and/or electronics. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the trigger as taught by Lintel with the hydrogel post as taught by Beebe et al for the purpose of having a self-regulating microfluidic device responsive to changes in value of a solution to regulate the feedback to compensate

and return the value of the solution to the desired level without the need for any external power sources and/or electronics.

11. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Couvillon, Jr. et al in view of Connelly et al (6689100). Couvillon, Jr. et al discloses the invention substantially as claimed (see above discussion) except for an adhesive for affixing the body to the individual. Connelley et al teaches that it is known to have an adhesive (38) for affixing the body to the individual for the purpose of preventing leakage and ensuring efficiency of the delivery (col 4, lns 34-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Couvillon, Jr. et al with the adhesive as taught by Connelly et al for the purpose of preventing leakage and ensuring efficiency of the delivery (col 4, lns 34-36).

Allowable Subject Matter

12. Claims 21-24 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments with respect to claims 1-8, 10-16, 18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blanco et al (5109850); Kriesel et al (6416495); Ziaie et al

(2004/0248326); Chuang et al (2003/0196900); Jiang et al (2006/0002804); Kriesel et al (5716343).

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER